Re-evaluation Note REV2008-07

1,3-Dichloropropene Mitigation Measures

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Executive Summary

This document provides an update to the Proposed Acceptability for Continued Registration (PACR) document PACR2004-34, Re-evaluation of *1,3-Dichloropropene*, published on 9 August 2004 by Health Canada's Pest Management Regulatory Agency (PMRA). Included in this document are 1) a summary of the data submitted by the registrant in response to the PACR, 2) a summary of comments received during the public comment period, and 3) the regulatory actions to mitigate risks and refine the assessment.

The PMRA's review of the groundwater monitoring studies submitted by the registrant together with additional information finds that, though not considered to constitute an imminent risk to health, concerns regarding infiltration to groundwater were not fully addressed by the submitted data. In response to the PMRA's request, the registrant has committed to conduct a groundwater monitoring study in major Canadian use areas during the spring of 2008 through 2009. The PMRA will consider results of this use-site-specific study and make the final decision. Regulatory action may be taken prior to study completion if warranted by interim study reports.

The PMRA has considered comments received during the public consultation period in taking this interim action.

1.0 Introduction

On 9 August 2004, Health Canada's Pest Management Regulatory Agency (PMRA) published the Proposed Acceptability for Continued Registration (PACR) document PACR2004-34, *Re-evaluation of 1,3-Dichloropropene*. This PACR document proposed to continue the registration of 1,3-dichloropropene (1,3-D) on an interim basis, provided that the specified mitigation measures and data requirements were addressed. The data required in the PACR were deemed necessary to address possible drinking water concerns.

In response to the data requirement in the PACR, the registrant submitted a number of groundwater monitoring studies conducted in the United States and Canada. The PMRA has reviewed these data. Based on additional information, in particular, a provincially mandated regional hydrogeological study that included the major use area in southern Ontario, the PMRA determined that only the results of a prospective groundwater monitoring (PGW) study in Wisconsin are relevant to Canada. The PMRA has also reviewed comments received during the public comment period. This document presents the assessment of data submitted by the registrant, a summary of comments received, and the regulatory actions.

2.0 Review Summary of Data Submitted in Response to PACR2004-34

PACR2004-34 for 1,3-D proposes risk mitigation measures to address the potential for leaching to groundwater. These measures include a prohibition of use in areas with Hydrologic Soil Group A soils, shallow groundwater or Karst geology; in other areas, a 31-m buffer is specified between the application area and any well used for potable water. The PACR also required that the registrant develop a protocol for a water monitoring program under Canadian use conditions. As part of its comments on the PACR, the registrant submitted a number of retrospective groundwater monitoring studies and a prospective groundwater monitoring (PGW) study conducted in Wisconsin, United States.

Data submitted by the registrant during the PACR comment period have not eliminated the PMRA's concern that 1,3-D may infiltrate to groundwater. Two Canadian studies were submitted. One study, conducted in the Abbotsford aquifer in British Columbia, was not found to be relevant to the current areas of use of 1,3-D in Canada. The second study, conducted in Norfolk County, was not adequate since only three monitoring wells were sampled, no information was provided on well depths or well locations relative to groundwater flow direction and application area, and the duration of sampling was insufficient.

The PMRA has considered the submitted monitoring studies together with additional information, in particular, a provincially mandated regional hydrogeologic study that included the Norfolk Sand Plain in southern Ontario. The Norfolk Sand Plain, which is characterized by Hydrologic Soil Group A soils, is the major tobacco-growing area and primary 1,3-D use area in Canada. This area has been identified in the regional hydrogeologic study as having high susceptibility to groundwater contamination due to its highly permeable soils underlain by a shallow, unconfined aquifer. The PMRA's review indicates that the environmental conditions (soils, hydrogeology, climate) in the tobacco-growing region of southern Ontario are very similar to those of the Wisconsin PGW study. Based on this similarity, the PMRA concludes that

the results of the Wisconsin PGW study are relevant to the major use area in southern Ontario. The PMRA has estimated potential 12-month average groundwater concentrations for southern Ontario based on the results of the Wisconsin PGW study.

Human exposure to a pesticide may occur through different routes (oral, dermal and inhalation) and pathways (dietary, drinking water, residential uses in and around homes and schools). To fully assess potential risks, the PMRA conducts aggregate assessments that consider these different pathways and routes. As 1,3-D has no residential uses and leaves no residues in or on food, the potential exposure from drinking water encompasses all sources of non-occupational exposure.

Exposure estimates derived from the Wisconsin PGW study are relevant to the major use area in Canada. The drinking water exposure estimates included 1,3-D and its two transformation products of concern, 3-chloroacrylic acid (CAAC) and 3-chloroallyl alcohol (CAAL), and ranged from 5.9 to 21.4 µg/L. These concentrations in drinking water represent lifetime cancer risk estimates of 1.3×10^{-5} to 4.7×10^{-5}. These risk estimates exceed the level of 1×10^{-6}, which is the current standard for the protection of health in the general population.

3.0 Summary of Comments Received During the Public Consultation Period

1) Growers, grower associations and the Ontario Ministry of Agriculture and Food expressed the following concerns.

- The groundwater advisory statement proposed in the PACR would mean that 1,3-D could not be used in the major tobacco and ginseng production areas in Ontario or for apple replant disease in Nova Scotia.

- The production of flue-cured tobacco and several other production practices in Ontario are based on fumigants containing 1,3-D. If 1,3-D cannot be used, the production methods may have to be changed.

- There are either no alternative products or, for some crops, the limited number of alternative products are currently or will soon be under re-evaluation.

- Buffer zones from occupied structures should be decreased to 31 m instead of the 100 m proposed in the PACR.

2) Environment Canada submitted the following comments.

- 1,3-D has been identified by the Technology and Economic Assessment Panel of the Montreal Protocol on Substances that Deplete the Ozone Layer as an alternative to methyl bromide. Methyl bromide consumption has been phased out through the Ozone-depleting Substances Regulations under the *Canadian Environmental Protection Act*, but there is provision for continued use where the use is deemed critical. Applications to Environment Canada for critical uses are to be made two years in advance. If the use of 1,3-D is to be restricted, Environment Canada requested that the timing of the restriction allow growers sufficient time to access alternatives.

Response to Comments

The PMRA will consider the concerns raised by these comments when implementing regulatory actions. It will work closely with affected users and stakeholders to identify transition needs and work with stakeholders toward a reasonable transition for uses that may be phased out as a result of the re-evaluation process.

Table 3.1 Major Uses of 1,3-D and Potential Registered Alternatives

Crop	1,3-D Use Frequency, Timing and Areas of Use	Potential Registered Alternatives[1]
Tobacco	Once every 2 years Spring application Southwest Ontario Note: Tobacco rotated yearly; therefore, application generally once every 2 years	**Chloropicrin** (soilborne diseases and nematodes) Will be under re-evaluation[3]
		Metam sodium[2] (nematodes) Will be under re-evaluation[3]
		Dazomet (soilborne diseases and nematodes)[4] Will be under re-evaluation[3]
Ginseng	At plant Approximately every 4 years Southwest Ontario	**Dazomet** (soilborne diseases and nematodes) Will be under re-evaluation[3]
		Fosetyl-aluminium (*Phytophthora*, foliar and root rot) Limited pest spectrum, not registered as soil fumigant.
		Metalaxyl-m (*Pythium* damping-off and *Phytophthora* root rot) Limited pest spectrum, not registered as soil fumigant
Strawberries	At plant Approximately every 3 years	**Chloropicrin** (soilborne diseases and nematodes) Will be under re-evaluation

Crop	1,3-D Use Frequency, Timing and Areas of Use	Potential Registered Alternatives[1]
Raspberries	At plant Approximately every 7 years	**Chloropicrin** (soilborne diseases and nematodes) Will be under re-evaluation
Carrots	Yearly	**None** (potential metam sodium)
Apple trees	At plant Approximately every 20 years	**None**

1 Excluding methyl bromide and methyl isothiocyanate, which are due for phase-out.

2 On the label for Vapam (metam sodium), it is recommended as a pre-planting treatment for the control of many of the soilborne pests that attack ornamentals, food and fibre crops, and tobacco. Therefore, it is a potential alternative for ginseng, strawberries, raspberries and carrots, but not effective in treating apple replant disease.

3 Chloropicrin, metam sodium and dazomet are scheduled for re-evaluation in 2008–2009. Chloropicrin is most often used in combination with other soil fumigants such as 1,3-D because it is more effective against fungal soil pathogens, but less effective against most nematodes.

4.0 Regulatory Actions to Mitigate Risk and Refine the Assessment

PACR2004-34 proposed several risk mitigation measures that were recommended by the United States Environmental Protection Agency in a 1998 Reregistration Eligibility Decision for 1,3-D. Many of these measures have already been applied to product labels. Registrants have been notified that the following interim measures are also required to be implemented prior to a final decision on 1,3-D:

- remove greenhouse uses
- revise environmental hazard label statements
- apply buffer zones from occupied structures and wells used for potable water
- include additional application instructions (i.e. closed-loading requirements, use of shut-off valves on application equipment)
- revise personal protective equipment requirements
- increase the restricted-entry interval from 72 hours to five days

Subsequent to publication of PACR2004-34, the PMRA learned that the vast majority of 1,3-D use occurs in areas considered potentially susceptible to infiltration of 1,3-D to groundwater. Based on current information available to the PMRA, estimates of long-term risk exceed current standards for the protection of health in the general population.

Nevertheless, 1,3-D is not considered to constitute an imminent risk to human health due to the following considerations: 1) the use pattern, 2) the nature of potential health concerns, and 3) the conservative approach taken in the risk assessment and potential for refinements in the PMRA's assessment. Water monitoring data specific to the use area would be useful to refine the assessment, and the registrant has committed to conduct a groundwater monitoring study in the tobacco-growing region of southern Ontario, which is the major 1,3-D use area. The study

protocols have been approved by the PMRA and data collection will begin in the spring of 2008. Groundwater sampling will be conducted six times during the study period from 189 private potable wells and 17 municipal drinking water supply wells. Study results will be accessible on the PMRA website as they become available. Therefore, interim results and intermediate reports will be generated during the study. The study will continue through 2009, and a final report is expected by 31 July 2010.

Based on the results of the groundwater monitoring study and a refined assessment using this study, the PMRA will make its final decision. The PMRA may take regulatory action prior to study completion if warranted by interim reports from the study.